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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,095	10/19/2001	Moses V. Chao	CHAO=10A	6779

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Washington, DC 20001

EXAMINER
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HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/982,095	<b>Applicant(s)</b> CHAO ET AL.	
	<b>Examiner</b> Robert C. Hayes, Ph.D.	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 1-8) in Paper No. 7/28/04 is acknowledged. The traversal is on the ground(s) that "as assays B and C are optional and used merely to confirm the results of assay A in the present claims as amended, applicants believe that the requirement for restriction is now moot and that all presently pending claims 1-12 should be examined together". This is not found persuasive because the methods of Groups II-IV remain distinct for the reasons previously made of record in Paper No: 20040628, in which claims 9-12 are alternatively directed to limitations for only assays B1, B2 and/or C. A serious burden, therefore, exists because of the different goals and method steps required for the search and examination of the claims of Groups II-IV, which are not required for examination of the method of Group I, similar to that argued by Applicants. Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 9-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7/28/04.

### ***Claim Rejections - 35 U.S.C. § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, the claims are incomplete because they do not define the step on how and when “and mediate neuronal cell survival” occurs, or when the step of “transactivates” occurs, as recited in the preamble (i.e., as it relates to claim 1). In addition, it is suggested that the second step of assay A be changed to “reacting the [a] neurotrophic receptor...” and the third step of assay A be changed to “antibody to the [a] phosphorylated form...” to more accurately claim the current invention.

Second, claims 4 & 8 are indefinite because PC12 cells are pheochromocytoma cells, and not “neuronal cells”, as currently recited. Likewise, N2a neuroblastoma cells” are tumor cells, and not “neuronal cells”; thereby, making claims 4 & 8 indefinite.

Third, claim 7 recites “wherein the neurotrophin receptor is a Ret receptor”, which is confusing because neurotrophins include NGF, BDNF, NT-3, NT-4/5, etc. (which all bind to Trk receptors), but does not include GDNF (which alternatively binds to the Ret receptor); thereby, making claim 7 indefinite (and also directed to a different invention). For example, see column 1 of Clary et al (U.S. Patent 5,753,225), and page 3 of the instant specification.

Fourth, because no reference sequence is recited in claim 5, it is unclear what exactly the recited position number for TrkA entails or means because, for example, it is unknown what species of TrkA is being referenced (in which different species have different sequences, by definition), and because any addition or deletion to a TrkA sequence can change the position number of the tyrosine residue to be phosphorylated; thereby, making claim 5 further indefinite.

Fifth, it is ambiguous what metes and bounds a “*small* molecule activator” entail, in which the term “small” in claim 1 is a relative term which renders the claim indefinite. The term “small” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Lastly, it is ambiguous what exactly “detecting *specific* binding” entails (i.e., as it relates to claim 1), in that no parameters defining what type of “*specific* binding” envisioned is recited in the claims. Nor is it clear when the relative term of “specific” is no longer specific; thereby, being indefinite.

***Claim Rejections - 35 U.S.C. § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Clary et al. (U.S. Patent 5,753,225).

Clary et al teach a method of screening for molecules (e.g., small activators when compared to big molecules), in which the cell lysate of treated PC12 cells (i.e., as it relates to claim 4, and therefore, also to base claim 1) are reacted with the anti-phosphotyrosine TrkA monoclonal antibody, 4G10 (i.e., as it relates to claims 2 & 3; columns 28 & 27), and where the

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relatively small molecule RtrkA.EX IgG is identified to phosphorylate the TrkA receptor, in the absence of the neurotrophin, NGF (i.e., as it relates to claim 1). Lastly, in that position 684 of TrkA is inherently phosphorylated after treatment with RtrkA.EX IgG (i.e., as also inherently phosphorylated after treatment with any neurotrophin), the limitation of claim 5 is reasonably anticipated; absence evidence to the contrary.

### *Conclusion*

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.  
November 1, 2004

**ROBERT C. HAYES, Ph.D.**  
**PATENT EXAMINER**